

domised controlled trials of psychological interventions, the results of this trial seem to be inconclusive.

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1 McArdle JMC, George WD, McArdle CS, Smith DC, Moodie AR, Hughson AVM, *et al.* Psychological support for patients undergoing breast cancer surgery: a randomised study. *BMJ* 1996;312:813-7. [With commentary by C Foster.] (30 March.)

### Support groups whose members have themselves had breast cancer are helpful

EDITOR,—Although all support groups have a useful role, it is a pity that the support group used in June M C McArdle and colleagues' study was not one whose members have all had breast cancer themselves and are specifically dedicated to supporting patients with breast cancer.<sup>1</sup> Members of such support groups can therefore truly empathise with the patients and also have the added advantage of being able to talk to patients not only about the feelings involved but also about the day to day practical problems experienced after leaving hospital.

In Edinburgh the breast care nurses quite often refer patients to our support group, Reach for Recovery, and value the reassurance and help that we can provide. We have been given the use of a room in the breast clinic, where nursing staff can bring patients immediately after they have received their diagnosis, while they are waiting to see the breast care nurses. This allows them to have a cup of coffee, a chat, and a quiet weep away from the public waiting area, and they are in a calmer and therefore more receptive frame of mind by the time they see the nurse counsellors. In addition, on a Wednesday morning we have a drop in centre, where patients can talk about their worries and concerns; this helps them to put everything into perspective. We are also allowed to visit patients in the breast cancer ward every Friday morning. This has been greatly appreciated by patients, and many long term contacts have been formed as a result of this short, informal, chat.

Feedback from patients indicates that they find our services helpful and a useful supplement to the medical team. They also find it reassuring to meet former patients who look both fit and "normal."

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### Patients' consent should have been sought

EDITOR,—It is ironic that a study in which informed consent was not sought<sup>1</sup> should be published in the same issue as an editorial by Richard Smith calling for action on misconduct in research.<sup>2</sup> The study falls well short of good clinical research practice, which is a requirement in trials sponsored by the pharmaceutical industry.<sup>3</sup> The hospital ethics committee was surely at fault in allowing the research to proceed in contravention of the Nuremberg Code.

In her commentary Claire Foster addresses some, but not all, of the issues of informed con-

sent raised by the study.<sup>1</sup> Women, unlike rats in cages, move around and communicate with each other. In the 1980s Evelyn Thomas, a lecturer in biology with the Open University who fully understood the principles of randomised controlled trials, found to her distress that she had been included in a trial of counselling versus no counselling after her mastectomy. Her case, which led to a formal complaint and was well publicised at the time, should have been a warning to future researchers.

The study raises further problems. It is imprudent for the lead researcher also to be the lead therapist. As Watson pointed out: "This is a major methodological flaw, as it is difficult to eliminate bias from a study where there is an obvious vested interest in the outcome."<sup>4</sup> The fact that two members of the same family are co-researchers should also give cause for concern. It is, moreover, a serious drawback that the voluntary organisation involved in the study, Tak Tent, was not functioning in its usual fashion; this in itself invalidates any conclusions.

A common complaint from cancer support groups is that hospitals act as gatekeepers, often not informing people of the groups' existence.<sup>5</sup> Patients should be free to refer themselves at any stage of their cancer journey, according to individual need. It is untrue that the effect of community based support organisations has not been evaluated: the reference that the authors give is out of date.

Breast care nurses do a valuable job; they have no need to compete with self help groups but should cooperate with them. They have limited time and rarely hold qualifications in counselling. They may therefore not pick up, or not be able to deal with, psychological morbidity. If as a result of this study they dismiss the work of voluntary groups and fail to inform patients of other sources of support, the study will have done harm rather than good.

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2 Smith R. Time to face up to research misconduct. *BMJ* 1996;312:789-90. (30 March.)

3 Official statements: good clinical trial practice. *Bull Med Ethics* 1996;114:10-1.

4 Watson M. Psychosocial intervention with cancer patients: a review. *Psychol Med* 1983;13:839-46.

5 Iveson P. A life turned upside down. *IJSM Network* 1995;2(24):4.

### Data may not have been summarised appropriately

EDITOR,—June M C McArdle and colleagues end their paper by saying that "the failure to reduce morbidity in the combined approach [routine care plus support from a breast care nurse and a voluntary organisation] is difficult to explain."<sup>1</sup> This logic is not supported by the data presented.

An overconcentration on P values at the expense of descriptive trends seems to have led the authors to conclude that "scores were consistently lower in patients offered support from [a] breast care nurse alone compared with the other groups, which were similar to each other." My interpretation of their data is that the poor showing of the combined approach is explained simply by two opposing effects, one larger than the other. Take, for example, their results for anxiety at 12 months. The means were 4.8 (routine care), 4.4 (routine care plus nurse only), 6.3 (routine care plus voluntary organisation only), and 5.8 (routine care plus

nurse and voluntary organisation combined). The effect of the nurse can be measured as  $4.4 - 4.8 = -0.4$  and as  $5.8 - 6.3 = -0.5$ . The effect of the voluntary organisation can be measured as  $6.3 - 4.8 = 1.5$  and as  $5.8 - 4.4 = 1.4$ . These effects combine to give more morbidity than if routine care alone is given. Similar conclusions can be drawn for most other measures reported at 12 months or averaged over four postoperative visits.

I recognise the dilemma in using parametric methods to summarise skewed distributions, with the resulting mismatch between presentation and results of statistical testing. Consequently, readers are presented with an inferior description of the trends. But how inferior? Is my manipulation of means justified? I have merely used my skills to interpret differently those means that the authors themselves regard as less than appropriate. My gut answer to my own questions is that means of skewed distributions do often characterise the appropriate message, but I would qualify this by saying that a more appropriate description should also have been given. In my experience, the main difficulty lies not in being able to summarise data more appropriately but in being able to do so within the confines of the space allowed.

A final point relates to inequality of loss to follow up in the study. At 12 months the loss was 24% for the routine care group compared with 6% (nurse only), 8% (voluntary organisation only), and 16% (combined). The psychological morbidity of those lost to follow up and of those who remained could have been different. This point should have been discussed in relation to the results.

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### Authors' reply

EDITOR,—We note Karin Friedli and Michael King's concern about baseline values. The large numbers and the randomisation process in our study make important differences in baseline self rating scales to the patients; thereafter it was often a member of the clinical team who did this. We agree that the person providing the support should not undertake a subjective assessment of the intervention. We felt, however, that self rating scales would circumvent this problem. We would have expected that, if the nurse had influenced the scores, the scores in the group who received support from both the nurse and the voluntary organisation would be similarly influenced, but they were not.

We agree with Helen Caulton that many women seem to benefit from support from a self help group whether the group consists of fellow sufferers or not. We would encourage self help groups, offering different approaches, to participate in randomised clinical trials. It is only by doing so that we will be in a position to define the best approach.

We note Heather Goodare's comments about the juxtaposition of our paper and the editorial by Richard Smith. We are not clear what she is implying. Is she suggesting that our results were falsified? At the time that this study was initiated (1987) there were no established breast care nurses in the west of Scotland. The ethics committee, the Cancer Research Campaign, and other respected authorities considered that informed consent was not necessary. Further-